510(K) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR 807.92 and the requirements of the Safe Medical Device ACT (SMDA) of 1990.

1. Sponsor Name
   Submitter's Name: Solace Therapeutics
   Address: 135 Newbury St, Framingham, MA 01701
   Phone: (508) 283-1200
   Contact Person: William Gruber
   Date of Preparation: May 30, 2013

2. Device Information
   Trade Name: Guardian Urethral Sheath
   Common Name: Urological catheter
   Class: II
   Classification Name: Urological catheter
   (21 CFR 876.5130, Product Code KNY)

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3. Predicate Devices
   Guardian Urethral Sheath K052298 (formerly CYSTOGLIDE INTRODUCER SHEATH)

4. Device Description
   The Solace Guardian Urethral Sheath is an everting sleeve sheath with a backflow valve for the establishment of a protective tract to the bladder to facilitate atraumatic insertion of catheters and instruments through the urethra. The sheath consists of a thin-walled rigid plastic tube, an obturator, and an everting sleeve that deploys from the obturator during insertion to reduce friction. Improvements from the Generation 1 sheath include a silicone disc to improve patient comfort at the external contact point, a single handed fluid management system, and independent fill and waste lines.

   The Urethral Sheath is supplied sterile and is single use. The working channel is sized to accommodate instruments up to 19 French. The sheath outside size is 24 French with a working length of 4.7 cm.

   The Sheath helps the patient by protecting the urethra and reducing abrasion or tenderness resulting from instruments passing through the urethra.

5. Intended Use
   The Guardian Urethral Sheath is intended to facilitate the introduction of catheters or instruments into the urethra. The Guardian Urethral Sheath is indicated for use as a guide for urological catheters or instruments inserted into the urethra and as a lubricious barrier between the urethral tissue and the catheter or instrument.

6. Comparison of Technological Characteristics

The Generation 2 Guardian Urethral Sheath is substantially equivalent in material, design and function to the Generation 1 Guardian Urethral Sheath K052298 (formerly CYSTOGLIDE INTRODUCER SHEATH)

Improvements from the Generation 1 sheath include a silicone disc to improve patient comfort at the external contact point, a single handed fluid management system, and independent fill and waste lines.

7. Performance Data
Biocompatibility Testing

Biocompatibility tests were conducted on the Guardian Urethral Sheath according to the requirements of ISO 10993:2009. The following were completed:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous reactivity

In Vitro Performance Testing

In vitro performance tests were performed on the Guardian Urethral Sheath. The following were performed:

- Simulated Use Testing
- Design Verification Testing
- Process Validation Testing

Conclusion
Based upon these biocompatibility and *in vitro* performance tests, the Guardian Urethral Sheath has been shown to be substantially equivalent to the currently marketed Guardian Urethral Sheath K052298.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2013

Solace Therapeutics
% William Gruber
President
135 Newbury Street
Framingham, MA 01701

Re: K131803
Trade/Device Name: Guardian Urethral Sheath
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KNY
Dated: July 23, 2013
Received: July 24, 2013

Dear William Gruber,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K131803

Device Name: Guardian Urethral Sheath

Indications For Use:

The Guardian Urethral Sheath is intended to facilitate the introduction of catheters or instruments into the urethra. The Guardian Urethral Sheath is indicated for use as a guide for urological catheters or instruments inserted into the urethra and as a lubricious barrier between the urethral tissue and the catheter or instrument.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K131803